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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,404	03/31/2004	Samuel Achilefu	MRD / 54DV	5388

7590

12/08/2006

David E. Jefferies
Wood, Herron & Evans, L.L.P.
2700 Carew Tower
441 Vine Street
Cincinnati, OH 45202-2917

EXAMINER

PERREIRA, MELISSA JEAN

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 12/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/814,404	Applicant(s) ACHILEFU ET AL.	
	Examiner Melissa Perreira	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-14 and 16-26 is/are pending in the application.
- 4a) Of the above claim(s) 4-14,16,18,20-22 and 24-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,17,19 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

It is acknowledged that claims 1,4-14,16-26 are pending in the application, claims 2,3 and 15 have been cancelled, claims 4-14 and 16 are withdrawn and that new claims 17-26 have been submitted in the reply filed on 11/14/06.

Information Disclosure Statement

The previously unconsidered non-patent literature documents have been not been considered for the IDS filed on 6/3/04 because they were not found in the parent application. The only information found in the parent application was the title pages and copyright information pages. The pertinent pages were not found and thus not considered.

Priority

Corrections to the bibliographic data sheet have been completed.

Response to Amendment

1. Newly submitted claims 18,20-22,24,25 and 26 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The species for the variable Y_1 , $-\text{CH}_2-(\text{CH}_2-\text{O}-\text{CH}_2)_1-\text{CH}_2-\text{CO}_2^-$, chosen in the reply to the election/restriction filed on 7/28/06 is different that the newly submitted species for the variable Y_1 , $-(\text{CH}_2)_a\text{NHSO}_3\text{T}$, $-\text{CH}_2-(\text{CH}_2-\text{O}-\text{CH}_2)_9-\text{CH}_2-\text{NH}_2$ and $-(\text{CH}_2)_h-\text{N}(\text{R}_a)-(\text{CH}_2)_l-\text{CO}_2\text{T}$ in the amendment to the claims filed on 11/14/06.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 18,20-22,24,25 and 26 are withdrawn

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from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Arguments

1. Applicant's arguments, see REMARKS, filed 11/14/06, with respect to ***Claim Rejections - 35 USC § 102*** claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Ohno et al. (US 4,839,265A) have been fully considered and are persuasive in light of the amendment to the claims. The rejection of claim 1 has been withdrawn.
2. Applicant's arguments, see REMARKS, filed 11/14/06, with respect to ***Claim Rejections - 35 USC § 102*** claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Southwick et al. (*OPPI Briefs*, 1988, 20, 279-284) have been fully considered and are persuasive in light of the amendment to the claims. The rejection of claim 1 has been withdrawn.
3. Applicant's arguments, see REMARKS, filed 11/14/06, with respect to ***Claim Rejections - 35 USC § 103*** claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Licha et al. (WO98/47538 as translated in US 6,534,041B1) in view of Achilefu et al. (US 6,180,085B1) have been fully considered and are persuasive in light of the amendment to the claims. The rejection of claim 1 has been withdrawn.
4. Applicant's arguments with respect to ***Claim Rejections - 35 USC § 102*** claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Licha et al. (WO98/47538 as

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translated in US 6,534,041B1) have been considered but are moot in view of the new ground(s) of rejection. The new grounds of rejection being necessitated by the amendment to the claims.

5. Applicant's arguments with respect to ***Claim Rejections - 35 USC § 102*** claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Achilefu et al. (US 6,180,085B1) have been considered but are moot in view of the new ground(s) of rejection. The new grounds of rejection being necessitated by the amendment to the claims.

New Grounds of Rejection

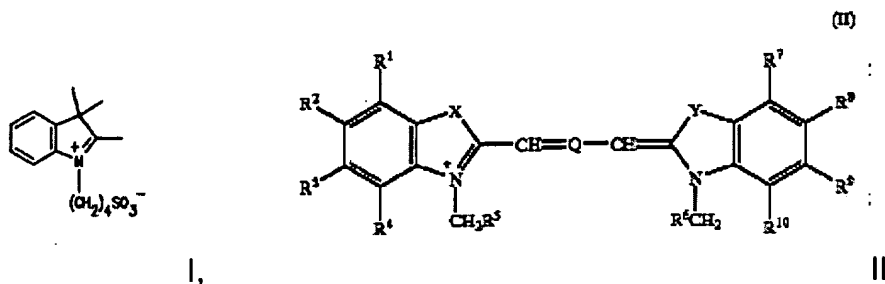
Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1,17,19 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Licha et al. (WO98/47538 as translated in US 6,534,041B1).

7. Licha et al. (WO98/47538 as translated in US 6,534,041B1) teaches of the compounds of formula II (below) which are prepared via intermediates, such as that of formula I (2,3,3-trimethyl-4,5-benzo-3H-indolene) (below) (Figure 1; column 11, lines 20-30).



8. R^5 of the composition of formula II may be a C_{1-50} alkyl chain interrupted by 0 to 15 oxygen atoms and/or 0 to 3 carbonyl groups and/or is substituted with 0 to 5 hydroxy groups, etc. (column 11, lines 36-53), i.e. polyhydroxyalkyl, polyalkoxyalkyl, etc. In order to generate the composition of formula II, the intermediate of formula I (2,3,3-trimethyl-4,5-benzo-3H-indolene) would be anticipated to contain the same R^5 substituent, i.e. polyhydroxyalkyl, polyalkoxyalkyl as the final product in place of the C_{1-4} sulfoalkyl chain. The resulting polyhydroxyalkyl, polyalkoxyalkyl, etc. substituted 2,3,3-trimethyl-4,5-benzo-3H-indolene intermediates of Licha et al. encompass the compositions of the instant claims, i.e. C_1 - C_{20} polyhydroxyalkyl substituted.

Claim Rejections - 35 USC § 103

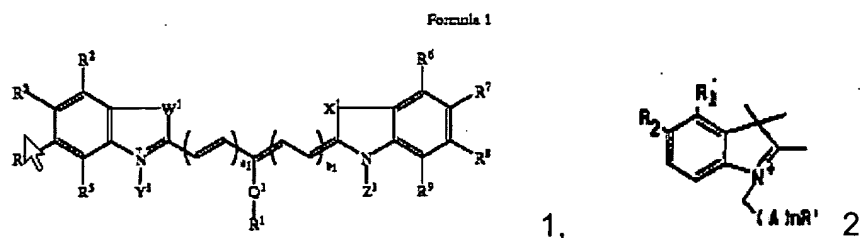
9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1,17,19 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Achilefu et al. (US 6,180,085B1).

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11. Achilefu et al. (US 6,180,085B1) discloses compositions of formula 1 (below) which are prepared via intermediates, such as that of formula 2 where R_1 and R_2 may be hydrogen (2,3,3-trimethyl-4,5-benzo-3H-indolene) (below) (fig 1, sheet 1; column 2, lines 45-54):



12. Y^1 of the composition of formula 1 may be $-\text{CH}_2-(\text{CH}_2-\text{O}-\text{CH}_2)_d-\text{CO}_2\text{H}$ or $-(\text{CH}_2)_e-\text{NH}_2$ or $-\text{CH}_2-(\text{CH}_2-\text{O}-\text{CH}_2)_f-\text{CH}_2-\text{NH}_2$, etc. column 2, lines 59-63) which encompass those substituents of the instant claims. At the time of the invention it would have been obvious to one ordinarily skilled in the art that in order to generate the final compositions of formula 1, the intermediate of formula 2 (2,3,3-trimethyl-4,5-benzo-3H-indolene) must be substituted with the same Y^1 , such as $-\text{CH}_2-(\text{CH}_2-\text{O}-\text{CH}_2)_d-\text{CO}_2\text{H}$ or $-(\text{CH}_2)_e-\text{NH}_2$ or $-\text{CH}_2-(\text{CH}_2-\text{O}-\text{CH}_2)_f-\text{CH}_2-\text{NH}_2$ in place of the $(A)_nR$ group. The $-\text{CH}_2-(\text{CH}_2-\text{O}-\text{CH}_2)_d-\text{CO}_2\text{H}$ or $-(\text{CH}_2)_e-\text{NH}_2$ or $-\text{CH}_2-(\text{CH}_2-\text{O}-\text{CH}_2)_f-\text{CH}_2-\text{NH}_2$ substituted 2,3,3-trimethyl-4,5-benzo-3H-indolene intermediates of Achilefu et al. (US 6,180,085B1) encompass the compositions of the instant claims.

Conclusion

No claims are allowed at this time.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

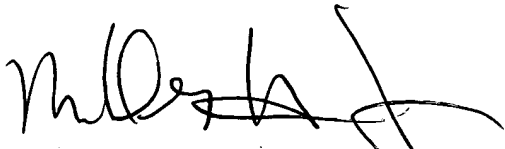
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MP

December 1, 2006



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER